

### **Remarks**

Claims 1, 3-34, 55-58, 60-63 and 65-73 are pending. Claim 2 has been canceled. Claims 1, 3, 70 and 72 have been amended. Claim 3 has been amended to reflect proper claim dependency. Claims 70 and 72 have been amended to correct typographical errors. No new matter has been added. The Applicants expressly reserve the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 U.S.C. §§ 120, 121.

### **Interview Summary**

Submitted herewith is an Interview Summary, dated June 6, 2008, prepared by the Applicant's former counsel, Dr. Patrick Waller (Reg. No. 41,418), corresponding to his in-person interview with the Examiner conducted at the Office on April 10, 2008.

### **Claim Rejections - 35 U.S.C. § 102(e)**

Claims 1-3, 13-16, 18-19, 24-25, 31-34, 55-58, 60-63, 65-67, and 69-72 stand rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,287,290 to Perkins et al. ("Perkins"). The Applicant respectfully traverses the rejection.

To anticipate a claim under §102, a reference must teach each and every element of the claim, either expressly or inherently. M.P.E.P. § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union oil Co. of California*, 8144. F. 2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Applicant submits that the cited art does not meet this standard.

Perkins teaches *optionally* sealing or occluding an air passage leading to the collapsed region of the lung by "delivering a plug..., typically at [*sic*] partially hydrated collagen hydrogel..." *after* the lung has been collapsed by vacuum aspiration or the application of external force. (See column 9, lines 24-29; column 10, lines 37-58; and Figure 4C)

In contrast, the Applicant's claimed methods relate to reducing lung volume in a patient by introducing material through a bronchoscope into a diseased alveolar region within the targeted region where the material induces collapse of the targeted region, promotes adhesion between one portion of the lung and another and promotes fibrosis in or around the collapsed region of the lung. Thus, the material does not serve merely as a plug to *occlude* the air passage leading to the collapsed tissue region as in Perkins, but acts to induce collapse, promote adhesion, and promote fibrosis. (See page 6, lines 25 to page 7, lines 1-3; and page 8, lines 17-23 of the specification as originally filed.)

Critically, Perkins does not teach or suggest promoting stable volume reduction of a target region of a patient's lung by introducing a material into a diseased alveolar region within the targeted region where the material induces collapse of the targeted region, promotes adhesion between one portion of the lung and another and promotes fibrosis in or around the collapsed region of the lung.

Therefore, Applicant respectfully requests the withdrawal of the claim rejections under 35 U.S.C. § 102(e).

**Claim Rejections - 35 U.S.C. § 103(a)**

*Perkins*

Claims 6-12 and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Perkins. The Applicant respectfully traverses the rejection.

To establish a *prima facie* case of obviousness, a number of criteria must be met. For example, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success in light of the cited reference or combination of references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); see MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The Examiner asserts that it would have been obvious to a skilled artisan "to provide the material listed in claims 6-12, since it has been held to be within the general skill of a worker in

the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design.” As discussed above, Perkins teaches delivering a plug to occlude an air passage leading to a region of the lung *after* the lung has been independently collapsed by vacuum aspiration or the application of an external force. One of ordinary skill in the art would not have been motivated to select the materials of Applicant’s claims as amended as the materials would be primarily localized in the sealing plug away from the diseased region of the lung and would not effectively serve their “intended use” (e.g., promoting fibrosis or vasoconstriction).

Furthermore, as discussed above, Perkins does not teach or suggest all of the limitations of Applicant’s amended claims.

Based on the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 6-12 and 28 under 35 U.S.C. § 103(a)

*Perkins in view of Edwardson*

Claims 4-5, 17, 20-21, 26-27, 29-30, 68, and 73 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Perkins in view of US Patent No. 5,739,288 to Edwardson et al. (“Edwardson”). The Applicant respectfully traverses the rejection.

The criteria for establishing a *prima facie* case of obviousness are outlined above. As discussed above, Perkins does not teach or suggest all of the limitations of Applicant’s amended claims. Critically, Edwardson does not cure the deficiencies of Perkins vis-à-vis the amended claims. The Examiner contends that “it would have been obvious to use the fibrin sealant of Edwardson in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery times.” Even if it were correct, which the Applicant does not concede, using the sealant disclosed by Edwardson in the methods taught by Perkins (i.e., as a plug to occlude an air passage leading to the lung *after* collapse) does not meet all of the limitations of the rejected claims, not would it lead one of ordinary skill in the art to conceptualize the claimed methods among those alternatives that would be “obvious to try.”

Furthermore, as discussed in MPEP § 2143.02 (VI), the proposed combination of references cannot change the principle of operation of a reference. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention

being modified, then the teaching of the references are not sufficient to render the claims *prima facie* obvious.” *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Applicants respectfully contend that in order to arrive at the methods of the rejected claims based on the combination of Perkins and Edwardson one of ordinary skill in the art would have to change the principle of operation of Perkins or Edwardson or both.

Therefore, the Applicants respectfully assert that the combination of Perkins and Edwardson does not render unpatentable the rejected claims. Based on the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 4-5, 17, 20-21, 26-27, 29-30, 68, and 73 under 35 U.S.C. § 103(a).

*Perkins in view of Edwardson and Antanavich*

Claims 22-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Perkins in view of Edwardson, and further in view of US Patent No. 5,814, 022 to Antanavich et al. (“Antanavich”). The Applicant respectfully traverses the rejection.

As discussed above, to establish a *prima facie* case of obviousness, a number of criteria must be met. For example, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success in light of the cited reference or combination of references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); see MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Antanavich discloses the design of an apparatus for accurately dispensing tissue sealants, one of which sealants may be “an adhesive protein solution having a fibrinogen content of from 3 to 12%.” The Examiner asserts that it would have been obvious to one of skill in the art “to provide the composition of fibrinogen from 3-12%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.” Antanavich does not cure the deficiencies of Perkins and Edwardson vis-à-vis the amended claims because the only relevant contribution from Antanavich to the Examiner’s obviousness rejection is the disclosure of an adhesive protein solution having a fibrinogen content from 3 to 12 %. The combination of Perkins and Edwardson, which is discussed in detail above, teaches only

delivering a plug (made of Edwardson's fibrin sealant) to occlude an air passage leading to a region of the lung *after* the lung has been independently collapsed by vacuum aspiration or the application of an external force. Therefore, the combination of Perkins, Edwardson, and Antanavich does not teach all the elements of the amended claims.

Based on the foregoing, the Applicants respectfully request the withdrawal of the rejection of claims 22-23 under 35 U.S.C. § 103(a).

### **Fees**

The Applicants believe they have provided for all required fees in connection with the filing of this Response. Nevertheless, the Commissioner is hereby authorized to charge any additional required fees due in connection with the filing of this Response to our Deposit Account, **06-1448** reference **ATX-011.03**.

### **Conclusion**

In view of the above amendments and remarks, it is believed that the pending claims are in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to contact the undersigned at (617) 832-1000.

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